American Lamb Council

American Sheep Industry Association, Inc.

American Wool Council

September 5, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm. 1-23
Rockville, MD 20857

Response to **Docket No. 97N-0217**
"Request For Comments on Development of Options to Encourage Animal Drug Approvals for Minor species and for Minor Uses"

We are writing on behalf of the American Sheep Industry Association (ASI). ASI represents the nearly 80,000 sheep producers in the United States through our 50 State-member associations as well as product manufacturers and other allied industry groups. ASI appreciates FDA/CVM's effort to solicit input on new approaches to improved minor species and minor-use drug availability.

Background

The Agency states that "Sheep are a minor species with respect to effectiveness and animal safety data collection requirements; sheep are a major species with respect to human safety data collection requirements from the possible presence of drug residues in food." For several years, FDA/CVM officials have repeatedly stated that the reclassification of sheep to minor species designation would take place in a short period of time. We have welcomed these announcements, but have been disappointed that the reclassification has not taken place. We oppose the continued designation of sheep as a major species with respect to human food safety data collection requirements and reiterate a summary of our previous arguments calling for reclassification. We believe that the per capita consumption of sheep meat in the United States at less than 1.5 pounds per year warrants minor species designation for sheep. We know of no data to support "the possible presence of drug residues in food" with respect to US domestic sheep products. We urge FDA to reconsider the designation of sheep as a major species with respect to human safety data collection requirements and, again we formally propose to reclassify sheep as a minor species.

We agree that in the absence of approved therapies, there are increased public health risks associated with the failure to treat sick animals. The extra-label use of therapeutic drugs is essential; however such usage, for many reasons, is not ideal or even a sufficient answer to treating sick animals under all scenarios.

97N-0217

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III A. Scope

In addition to our arguments listed above for reclassification of sheep to minor species with respect to human food safety data collection requirements, we suggest that the Agency consider using human food safety data extrapolation from "like" major species for minor species. An example would be to extrapolate ovine values from bovine data.

III B. Creating Additional Statutory Authority

It was our hope that the ADAA would provide an adequate statutory framework so that the Agency could propose rulemaking that could affect the needed changes in the minor species and minor-use drug approval process in order for desperately needed products to be labeled and enter the market place. We suggest that the Agency avoid seeking additional statutory authority where adequate regulatory solutions can be found. With regards to answering the specific questions stated in the docket, we believe that there should be different standards for target animal safety and effectiveness and for human food safety for new animal drugs intended for minor species or for minor uses. We believe that if the determined safety and effectiveness standards criteria were satisfactorily met there would be no need for product labels to reflect the use of different standards. We believe that dose, residue depletion, and withdrawal times, can be effectively determined by the interpolation of data from closely related species; i.e., dosage, residue depletion and withdrawal times for sheep could be extrapolated from cattle data using body weight as the basis. Research data have shown that residue depletion times vary to a greater degree within the bovine species than the variation of residue depletion time between bovine and ovine species.

We believe that conditional approvals with postmarket surveillance could be coupled with standards for approval of minor use/minor species drugs. Such an arrangement would be very useful for minor species and minor-use drug availability; not necessarily as a substitute for different premarket safety and effectiveness studies but as a part of the approval process. If appropriate human food safety data are obtained, target animal safety and effectiveness data requirements could, in part, be fulfilled through postmarket surveillance. In this case, it would be necessary for product labeling to reflect conditional status.

We believe that the act should be amended to allow foreign reviews and approvals. The very nature of our free global market economy insists that we use data from other parts of the world. Transparency of records, standards setting and free access to data coupled with a certification of review processes should provide FDA and Congress the verification of data integrity needed to be as confident in foreign reviews and approvals as they are in our own.

Primary (third party) reviews that are external to FDA/CVM could be used in addition to or in place of reviews by the Agency. Expert panels that are sanctioned by the Agency, such as is mentioned in the notice, for determinations of safety and effectiveness could serve this purpose.

Compendia could also be useful where the criteria are fairly clear such as in the case where extrapolation of major species data was applied to minor species.

III C. Administrative and Regulatory Changes

Standards for manufacturing drugs for minor uses or minor species could be different than those for major species. Different standards should not be construed to mean "lower standards". Instead, the emphasis should be on quality and purity of the final product rather than requiring a lock-step procedure for each segment of the manufacturing process. The use of HACCP principles could provide the mechanism for changing standards.

Strategies to coordinate the development, application and approval process similar to those used for drugs for aquatic species could be used for minor species and minor use approvals. End users as well as pharmaceutical firms have an interest in both the health of animals and residue avoidance in the resulting animal products. Most end users would welcome the opportunity to become involved with the approval process and educational programs.

III D. Creating Incentives

Economic incentives are the key to encouraging pursuit of approvals or supplemental approvals for minor species and minor uses. Tax breaks, grants, and market or label exclusivity are all valid methods of providing economic incentives. We suggest a combination of these incentives be put in place for all classes of new animal drugs with special consideration for food producing species.

The NRSP-7 program is a useful mechanism for minor species and minor use approvals but has had limited success. NRSP-7 has been grossly under funded in terms of addressing the needs of minor species and minor use therapeutics and reproduction drugs for food and fiber producing animals. We believe that other changes in the approval process as described elsewhere in these comments should be used along with a more adequately funded NRSP-7 for both therapeutic and production drug approvals for minor species and minor uses. NRSP-7 could be expanded to include non-food/fiber species. However, we believe that an expansion should be considered only if the needs of food/fiber species are adequately met. Philanthropic, public interest and other not-for-profit organizations should be encouraged to new animal drug development research. This will occur if economic incentives are put in place to encourage the private sector to invest in minor species and minor use approvals. The Agency could initiate investment by such groups by setting up a "matching fund" program perhaps through NRSP-7 to address industry identified priority product approvals.

III E. Extending Existing Legal Authority

We believe that the Veterinary Feed Directive (VFD) is a valid and useful method of providing drugs through feeds. We support current efforts of the Minor Species Coalition to extend the scope of VFD drugs to include their use in minor species without requiring a review process that is too extensive.

The need for reproductive drugs/products is more critical today than ever in US food/fiber animal production. Since many of our global trading partners have access to these products, it is difficult for U.S. producers to remain competitive without the same advantage. Also, a number of new technologies now available to food/fiber animal production cannot be used without these products. Examples are embryo transfer and artificial insemination in sheep. We believe it is very important to extend the Agency's authority to streamline and fast-track approvals for these products. Unlike antibiotics, these products carry a different set of concerns with regards to effectiveness and safety. Although extra-label usage under Veterinary supervision is needed as a stopgap measure, label approval would be the most practical and economical approach to assuring U.S. competitiveness in global markets without compromising proper usage.

We appreciate the opportunity to present these comments and we look forward to working with FDA/CVM in finding new, effective approaches to minor species and minor-use drug availability. Whenever the sheep industry can be of assistance to the Agency, please don't hesitate to contact us.

Sincerely,

Steve Raftopoulos
President

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